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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/701,572

Applicant(s)

KONDOROSI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on September 17, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-2, 8-15, 17, 19-28 and 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15, 17, 19-28, 30 and 32-41 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's amendment filed on June 1, 2004 has been entered.

Claims 3-7, 16, 18 and 29 are cancelled.

Claims 1-2, 8-15, 17, 19-28 and 30-41 are pending.

Claims 1-2 and 8-11 are withdrawn.

Claims 12, 15 and 19 are currently amended.

Claims 12-15, 17, 19-28 and 30-41 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Priority***

A certified copy of French application 98 071774 has been received in this National Stage application from the International Bureau.

### ***Claim Rejections - 35 USC § 112***

Claims 15, 30 and 32-39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 30, 2004.

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Applicant's arguments filed June 1, 2004, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn in view of the amendment of independent Claim 12 to describe the claimed nucleic acid sequences structurally (by reference to SEQ ID NO: 1 or 2) and functionally (by reference to their ability to encode polypeptides that inhibit mitosis and induces endoreplication). Applicant points out that, in accord with the Description Guidelines, Claim 12 now refers to sequences with a high degree of structural similarity, because they either encode the full-length polypeptide of SEQ ID NO: 2, or hybridize to the coding region of SEQ ID NO: 1 under stringent conditions. Moreover, Applicant points out that the claims are now directed to sequences which encode polypeptides which inhibit mitosis and endoreplication. Applicant submits that in view of the high level of skill in the art, the structural definition in combination with the coding function of DNA are adequate to determine that the Applicant had possession of the invention as of the filing date. (reply pages 6-7).

The rejection is maintained because the rejected claims continue to be directed to a genus of sequences that are not adequately described. The amendment of independent Claim 12 to describe the claimed nucleic acid sequences structurally and functionally is not pertinent to the description of rejected claims 30 and 32-39, as rejected claims 30 and 32-39 do not depend from claim 12. Applicant has not described functions for all sequences that would hybridize to SEQ ID NO:1 under the conditions set forth in claim 30, since Applicant has only described a sense sequence (SEQ ID NO:1) that encodes a protein that inhibits mitosis and induces

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endoreplication, and an antisense sequence (the 1.2 kb SstI-PvuII fragment of SEQ ID NO:1) that inhibits the expression of a protein that inhibits mitosis and induces endoreplication.

Additionally, with respect to rejected claim 15, Applicant has not described WD40 repeat comprising fragments of SEQ ID NO:2 that would function to inhibit mitosis and induce endoreplication, and the ability of one skilled in the art to make such fragments would not substitute for a description of such fragments, as even a showing of possession alone would not cure a lack of written description (*Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617).

Claims 15, 30 and 32-39 remain rejected remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO:1 that encodes a protein that inhibits mitosis and induces endoreplication, and for an isolated nucleic acid comprising the 1.2 kb SstI-PvuII fragment of SEQ ID NO:1 that inhibits the expression of a protein that inhibits mitosis and induces endoreplication, and for functional sequences that hybridize thereto under the specified stringency conditions, does not reasonably provide enablement for other fragments of SEQ ID NOS:1 or 2, or for sequences encoding other polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed January 30, 2004.

Applicant's arguments filed June 1, 2004, have been fully considered but they are not persuasive.

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Applicant argues that the rejection should be withdrawn in view of the amendment of independent Claim 12 to describe the claimed nucleic acid sequences structurally (by reference to SEQ ID NO: 1 or 2) and functionally (by reference to their ability to encode polypeptides that inhibit mitosis and induces endoreplication). Applicant points out that, in accord with the Description Guidelines, Claim 12 now refers to sequences with a high degree of structural similarity, because they either encode the full-length polypeptide of SEQ ID NO: 2, or hybridize to the coding region of SEQ ID NO: 1 under stringent conditions. Moreover, Applicant points out that the claims are now directed to sequences which encode polypeptides which inhibit mitosis and endoreplication. Applicant submits that in view of the high level of skill in the art, the structural definition in combination with the coding function of DNA are adequate to determine that the Applicant had possession of the invention as of the filing date. (reply pages 6-7).

The rejection is maintained because the rejected claims continue to be directed to a genus of sequences that are not fully enabled. The amendment of independent Claim 12 to recite the structure and function of the claimed nucleic acid sequences is not pertinent to the enablement of rejected claims 30 and 32-39, as rejected claims 30 and 32-39 do not depend from claim 12. Applicant has not taught uses for all sequences that would hybridize to SEQ ID NO:1 under the conditions set forth in claim 30, since Applicant has only disclosed the use of a sense sequence to express a protein that inhibits mitosis and induces endoreplication, and the use of an antisense sequence to inhibit the expression of a protein that inhibits mitosis and induces endoreplication.

Additionally, with respect to rejected claim 15, Applicant has not provided sufficient guidance with respect to which WD40 repeat comprising fragments of SEQ ID NO:2 would

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function to inhibit mitosis and induce endoreplication and which would not. Absent such guidance one skilled in the art would have to test every WD40 repeat comprising fragment of SEQ ID NO:2 to discriminate between those fragments that would function to inhibit mitosis and induce endoreplication and those that would not. Though the level of skill in the biotechnological arts is considered to be high, such trial and error testing of all WD40 repeat comprising fragments of SEQ ID NO:2 would nonetheless constitute undue experimentation.

Claim 12, and claims 13-15, 17, 19-28 and 40-41 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “(SEQ ID NO:2)”. It is unclear whether the limitations enclosed in the parentheses are part of the claimed invention. It is suggested that the claim be amended to delete the parentheses in order to overcome the rejection.

Claim 17 remains rejected, and claim 12 and claims 13-15, 17, 19-28 and 40-41 dependent thereon, are rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the acronym “CCS52Ms”, for the reasons of record set forth in the office action mailed January 30, 2004.

Applicant's arguments filed June 1, 2004, have been fully considered but they are not persuasive.

Applicant argues that the rejection is moot in view of the claim amendments (reply page 7).

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The rejection is maintained because the amendment of claim 12 to recite that CCS52Ms “is a polypeptide having 475 amino acids of *Medicago sativa*” does not clarify what “CCS52Ms” is meant to designate. The limitation does not specify the identity of the 475 amino acids, or their sequential arrangement, such that the limitation reads on any polypeptide having any 475 amino acids in any sequential arrangement that is encoded by a sequence that hybridizes under stringent conditions to the full-length complement of the coding portion of SEQ ID NO:1. That the 475 amino acids are “of *Medicago sativa*” also does not clarify what “CCS52Ms” is meant to designate, as *Medicago sativa* contains the same types of amino acids that other organisms contain.

Claim 19 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the acronym “CCS52Mt”, for the reasons of record set forth in the office action mailed January 30, 2004.

Applicant's arguments filed June 1, 2004, have been fully considered but they are not persuasive.

Applicant argues that the rejection is moot in view of the claim amendments (reply page 7).

The rejection is maintained because the amendment of claim 19 to recite that CCS52Mt “is a polypeptide having 475 amino acids of *Medicago trunculata*” does not clarify what “CCS52Mt” is meant to designate. The limitation does not specify the identity of the 475 amino acids, or their sequential arrangement, such that the limitation reads on any polypeptide having any 475 amino acids in any sequential arrangement that is encoded by a sequence that hybridizes



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under stringent conditions to the full-length complement of the coding portion of SEQ ID NO:1. That the 475 amino acids are “of *Medicago trunculata*” also does not clarify what “CCS52Mt” is meant to designate, as *Medicago trunculata* contains the same types of amino acids that other organisms contain.

***Allowable Subject Matter***

Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Examiner  
Art Unit 1638

CC



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